ISSUES MANAGEMENT PROGRAM MANUAL

LBNL/PUB-5519 (1), Rev. 4

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REVISION HISTORY

Revision	Date	Revision Description
1	9/1/08	Minor revision: incorporate report template for Corrective Action Plans, Extent of Condition Reviews and Effectiveness Reviews; clarify who to contact when such reviews are required; clarify definitions; and clarify hierarchy of issues.
2	9/4/08	Minor revision: clarify extension request policy.
3	5/1/10	Major revision: Streamline process by eliminating redundancy and replace multiple "issue types" with single issue type to focus on the Risk Level Graded Approach, and incorporate Issues Management Program Staffing Model elements.
4	9/23/11	Major revision: Reformat to better describe program elements, roles and responsibilities; refine the process of corrective action development and incorporated the revised process for performing Effectiveness Reviews.

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1.0 Program Description

The Lawrence Berkeley National Laboratory (LBNL) Issues Management Program encompasses the documentation, tracking and resolution of issues, verification of corrective action closure, and validation of corrective actions effectiveness. The program also includes identification/monitoring, analysis and correction of adverse trends, and mechanisms for continuous feedback and performance improvement.

Issues that are governed by this Program include program and performance non-compliance or deficiencies, findings that may be identified through employee discovery, internal or external assessments, adverse conditions that meet internal and external reporting requirements, and suggested process improvements. The scope of these issues includes all severity levels, ranging from high to de minimus significance.

The Issues Management Program elements include:

- *Entering Issues and Corrective Actions in the CATS Database*

- *Performing Causal Analysis*
  a) Root Cause
  b) Apparent Cause

- *Performing Extent of Condition Reviews*

- *Managing and Implementing Corrective Actions through the CATS Database*
  a) Development of Corrective Action/Plan
  b) Verification of Completion
  c) Issue Closure

- *Performing Effectiveness Reviews*

- *Developing and Disseminating Lessons Learned / Best Practices*

- *Performing Data Monitoring and Analysis*

2.0 Persons Affected

All LBNL personnel are responsible for identifying issues that may require correction.

3.0 Exceptions

Personnel-sensitive issues such as, but not limited to, allegations of harassment, intimidation, retaliation and discrimination, and employee/employer relationship issues are not managed through the Issues Management Program. These issues should be identified and managed via an appropriate process, such as employee concerns or human resources. Likewise, these issues are not entered in the CATS database.

4.0 Program Requirements

The LBNL Issues Management Program encompasses the continuous monitoring of work programs, performance and safety to promptly identify issues and their causes, and to identify and effectively implement corrective actions to ensure successful resolution and prevent the same or similar problems from occurring.

A "no-fault" attitude is fostered by management to encourage their staff to report issues. A graded approach is used in the application of Issues Management Program elements. This allows management to prioritize and focus resources in a manner that best addresses the issues having the greatest risk for:

- Affecting the ability to meet contract and regulatory requirements.
- Adversely impacting the reliability of LBNL mission and operations.
- Adversely impacting the environment, public and employee safety and health.

Application of the Issues Management process includes the following:

4.1 Graded Approach

Issues management is performed using a graded approach that is based on the risk level assigned to an issue to ensure that the appropriate levels of analysis, corrective action development and documentation are commensurate with Federal and LBNL standards and regulations. ***A description of each risk level is found in Attachment 8, Risk Level and Significant Guidance on page 36 in this manual.*** The graded approach is outlined in Table 1, below.

Table 1 – Issues Management Program Graded Approach

Issue Risk Level	Enter in CATS/ Track to Resolution	Cause Analysis	Extent of Condition	Corrective Action Plan	Verify Completion	Effectiveness Review	Lessons Learned
High	X	Root	X	X	X	X	X*
Medium	X	Root or Apparent as DBM	DBM	DBM	X	DBM	DBM
Low	X	Apparent as DBM	--	--	--	--	DBM
De Minimus	X	--	--	--	--	--	--

DBM = Determined by Management
* = Required for ORPS Category 1 or Recurring, and DOE Type A or B incidents.

4.1.1 CATS Database (CATS) Entry

1. All issues and associated corrective actions, regardless of risk level, must be entered and tracked through resolution in the CATS Database. The

requirements and instruction for entering issues and corrective actions into CATS are found in the OIA-OCA-0001, Rev.3 *Corrective Action Tracking System (CATS) Database User Manual*. **Note:** Documenting issues that are immediately-corrected or fixed upon identification ("on-the-spot") is a recommended practice. However, the decision to document these issues in CATS is at the discretion of Division Management.

- Issues and associated corrective actions must be entered into the CATS Database as soon as practical after identification, but no later than five (5) business days after identification. Issues can be entered simultaneously with the associated corrective action(s).

- While some Causal Analysis may be required (e.g. RCA, Accident Investigations, etc.), issues must be entered into the CATS database as soon as there is reasonable confidence that the issue exists and that it can be characterized.

- The entry of observations or recommendations into the CATS database is left to the discretion of the Division Management.

- An extension request for a corrective action that cannot be completed by the original due date must be entered in CATS at least two weeks (14 days) in advance of the current due date to be considered for approval. The detailed requirements and instructions for making extension requests are found in Attachment 2 – *Extension Requests* in this manual.

4.1.2 Causal Analysis

- A Root Cause Analysis (RCA) must be performed for all High Risk level issues using a formal methodology in accordance with LBNL/PUB 5519(2), *Causal Analysis Program Manual*.

- A RCA or an Apparent Cause Analysis may be performed for Medium Risk level issues, as determined by management, in accordance with LBNL/PUB 5519(2), *Causal Analysis Program Manual*.

- An Apparent Cause Analysis may be performed for Low Risk level issues, as determined by management.

- The Office of Contractor Assurance (OCA) must complete a quality assurance review of all High Risk level issue RCA Reports.

- OCA may perform a quality assurance review of Medium or Low Risk level RCA or Apparent Cause Analysis Reports at management discretion.

4.1.3 Extent of Condition Review

- Extent of Condition (EOC) reviews are required for all High Risk level issues because of their seriousness and importance.

- EOC reviews for less significant issues may be initiated at the discretion of a Cognizant Manager to ensure corrective and preventive actions are effectively developed or to identify opportunities for improvement.

- An EOC review may be documented as part of the Causal Analysis Report or in a separate document. The detailed requirements and instructions for performing an EOC are found in Attachment 3 – *Extent of Condition Review Guidance* in this manual.

4.1.4 Corrective Action Plan Development

- A Corrective Action Plan (CAP) is required for all High Risk level issues. CAPs for less significant issues may be developed at the discretion of a Cognizant Manager.

- For High Risk level issues that are Occurrence Reporting Processing System (ORPS) Category 1, 2 or Recurring and Price Anderson Amendment Act (PAAA) Non Tracking System (NTS)-reportable incidents, the finalized ORPS/NTS report may constitute the formal CAP.

- At management's discretion, findings that are a result of a formal assessment may require a CAP.

- CAPs should be completed as soon as practical in accordance with Attachment 5 – *Corrective Action Plan Development and Template* in this manual.

- OCA must complete a quality assurance review of all High Risk issue CAPs, including those where the ORPS/NTS report serves as the formal CAP.

4.1.5 Corrective Action Completion Verification

- A verification of corrective action(s) closure is performed for High and Medium Risk levels issues.

- The closure verification is performed by someone who did not complete/implement the corrective action.

- The verification must confirm that the corrective action addresses the issue and is completed as required, and that objective evidence exists to demonstrate completion.

- Once the verification has been completed, the corrective action can be designated as completed in the CATS Database.

4.1.6 Effectiveness Review

- Effectiveness reviews must be performed for High Risk level issues. Effectiveness Reviews may be performed on Medium Risk level issues at management discretion.

- The effectiveness review of corrective actions should be performed 6 to 12 months after issue closure in accordance with Attachment 6 – *Effectiveness Review Guidance* in this manual.

4.1.7 Lessons Learned

- A Lessons Learned briefing must be developed and submitted to the LBNL Lessons Learned and Best Practices Database for High Risk level issues that are ORPS Category 1 and Recurring incidents, and DOE Type A and B incidents.

- Lessons Learned briefings also should be developed and submitted to the LBNL Lessons Learned and Best Practices Database when issues or events have a significant impact on safety and operations, and/or may be applicable to other national laboratories across the Department of Energy (DOE) complex.

- The Briefings should be developed and submitted in accordance with LBNL/PUB 5519(4), *Lessons Learned and Best Practices Program Manual*.

4.1.8 Data Monitoring and Analysis

- Data analysis and trending activities are performed to help monitor and analyze issues, trends of vulnerabilities at a lower risk level, and areas of improvement for quality, efficiency and reliability.

- Data monitoring and analysis is performed in accordance with LBNL/PUB-5519 (3), *Data Monitoring and Analysis Program Manual.*

5.0 Implementing Documents

5.1 BASELINE DOCUMENTS

- Contract 31, Section H.30, Contractor Assurance
- LBNL/PUB-3111, *Operations and Quality Management Program*
- LBNL/PUB-5520, *UC Contractor Assurance System Description*

5.2 REFERENCE DOCUMENTS

- LBNL/PUB-3032, *Property Manual*
- LBNL/PUB-3000, Chapter 15, *Occurrence Reporting*
- LBNL/PUB-5519 (2), *Root Cause Analysis Program Manual*

- LBNL/PUB-5519 (3), *Data Monitoring and Analysis Program Manual*
- LBNL/PUB-5519 (4), *Lessons Learned and Best Practice Program Manual*
- *Regulations and Procedures Manual*
- *Audit Resolution and Follow-Up*
- *Laboratory Procurement Standard Practices Manual,* Section 46.1, "Subcontract Quality Assurance"
- *Manual for PAAA Program Communications, Oversight and Reporting Processes*
- *Manual for 10 CFR 851 Worker Safety & Health Program Noncompliance Screening & Reporting Process*
- *Radiation Protection Program for the Lawrence Berkeley National Laboratory*

6.0 Recordkeeping Requirements

The following are records that are generated as a result of implementing program requirements. The records shall be maintained in accordance with the requirements outlined in the Regulations and Procedures Manual (RPM):

- CATS Database Entries
- Root Cause Analysis Reports
- Apparent Cause Analysis Reports
- Extent of Condition Reviews (may be included in the RCA Report)
- Corrective Action Plan
- Effectiveness Review Analyses and Reports
- Lessons Learned / Best Practices Briefings
- Performance Analysis Report of PAAA NTS and ORPS Reportable Incidents

7.0 Roles and Responsibilities

Overarching roles and responsibilities for the Issues Management Program:

- Laboratory Management is responsible for communicating and reinforcing the importance of proactively reporting and managing issues.

- Division Management is responsible for ensuring that personnel are adhering to the requirements outlined in this Program Manual.

- OCA provides oversight and administration of the Issues Management Program, which includes maintaining and revising this program manual, maintaining the CATS and Lessons Learned Databases, and providing technical guidance to LBNL staff with regard to the Issues Management Program.

Specific roles and responsibilities for the Issues Management Program elements:

DIVISION DIRECTOR

IMP ELEMENTS	RESPONSIBILITIES
CATS Database	• Ensures that issues and associated corrective action(s) are entered into the Corrective Action Tracking System (CATS) database and managed through resolution.
Causal Analysis Extent of Condition Review	• In conjunction with OCA, selects RCA and EOC Review team(s), for issues that his/her respective organization owns in accordance with LBNL/PUB 5519(2), *Causal Analysis Program Manual*. EOC is performed in accordance with Attachment 3 – *Extent of Condition Review Guidance* in this manual, if applicable. • Charters the RCA and EOC Review team(s) for issues that his/her respective division owns prior to initiation of the RCA and EOC Review activities.
CAP Development	• Ensures that a CAP is developed and approved for all High Risk level issues and approves the CAP in accordance with Attachment 5 – *Corrective Action Plan Development and Template.* • Ensures that OCA performs a quality assurance review of the CAP for High Risk level issues prior to distribution and implementation. • Determines if the CAP for High Risk level issues will be submitted to the DOE.
Effectiveness Reviews	• In conjunction with OCA, selects Effectiveness Review team members for High Risk level issues that his/her respective division owns. • Charters Effectiveness Review Teams prior to initiation of the Effectiveness Review activities. • Approves the Effectiveness Review Report. • Determines additional corrective actions that will be developed and implemented as a result of an Effectiveness Review, if applicable. • Ensures that any additional corrective actions as a result of an Effectiveness Review are entered into the CATS Database.

COGNIZANT MANAGER

IMP ELEMENTS	RESPONSIBILITIES
CATS Database	• Ensures that issues and associated corrective action(s) are entered into the Corrective Action Tracking System (CATS) database and managed through resolution.
Causal Analysis	• Notifies the OCA Manager, appropriate PAAA and ORPS Coordinators, and EHS Division Director to determine if the issue is a Significant Adverse Condition or externally reportable, as follows: a) OCA Manager: Significant Adverse Condition b) PAAA Coordinator: PAAA Reportability c) ORPS Coordinator: ORPS Reportability d) EHS Division Director: Type A or B Reportability • Notifies Senior and affected management of any Significant Adverse Conditions, PAAA NTS-reportable incidents, ORPS category 1, 2 or R incidents, and Type A and B accidents. • Based on the reviews performed by the OCA, EHS Division Director, and/or the ORPS and PAAA Coordinators, determine the Risk Level of the issue. • If the issue is not a High Risk level, determine if the issue requires a Causal Analysis and EOC Review. • Initiates Root or Apparent Cause Causal Analysis for Medium Risk level issues, as appropriate, in accordance with LBNL/PUB-5519(2). • Initiates Apparent Cause Causal Analysis for Low Risk level issues, as appropriate.
Extent of Condition Review	• Initiates Extent of Condition reviews for Medium Risk level issues, as appropriate.
CAP Development	• Ensures that a CAP is developed and approved for Medium Risk level issues, as applicable, and approves the CAP in accordance with Attachment 4. • Determines if the CAP for Medium Risk level issues will be submitted to the DOE.
Corrective Action Completion Verification	• Assigns independent personnel to perform verification of completed corrective actions, as appropriate.

IMP ELEMENTS	RESPONSIBILITIES
	• Ensures objective evidence of completed corrective actions is available for review or uploaded into the CATS Database, as applicable.
Effectiveness Reviews	• Initiates Effectiveness Reviews for Medium Risk level issues, as appropriate. • Charters Effectiveness Review Teams for Medium Risk level issues prior to initiation of the Effectiveness Review activities. • Determines additional corrective actions that will be developed and implemented as a result of an Effectiveness Review for Medium Risk level issues, if applicable. • Ensures that any additional corrective actions as a result of the Effectiveness Review are entered into the CATS Database for Medium Risk level issues.
Lessons Learned	• Ensures that Lessons Learned briefings are generated for High Risk level issues, as applicable. • Determines the need for and ensures that other Lessons Learned or Best Practice briefings are initiated, in accordance with LBNL/PUB-5519 (4), as applicable.
Data Monitoring & Analysis	• Ensures data monitoring and analysis are performed in accordance with LBNL/PUB-5519 (3), as necessary.

OCA

IMP ELEMENTS	RESPONSIBILITIES
CATS Database	• Monitors overdue corrective actions and escalates concerns to senior management for resolution, as necessary. • Approves extension requests for High and Medium Risk level issues.
Causal Analysis	• Determine if the issue meets the criteria for Significant Adverse Condition (Refer Attachment 1 – *Definitions / Acronyms*). • Notifies affected organizations of Significant Adverse Condition implications. • In conjunction with the Division Director, selects the RCA and

IMP ELEMENTS	RESPONSIBILITIES
	EOC Review team(s), for High Risk level issues. • Performs a quality assurance review of RCA reports for all High Risk level issues prior to completion and distribution. • Performs a quality assurance review of RCA reports for Medium Risk level issues, at management discretion, prior to completion and distribution.
Extent of Condition Review	• Performs a quality assurance review of EOC reviews for all High Risk level issues prior to completion and distribution. • Performs a quality assurance review of EOC reviews for Medium Risk level issues, at management discretion, prior to completion and distribution.
CAP Development	• Performs a quality assurance review of all High Risk level CAPS prior to completion and distribution, including those documented in ORPS or PAAA NTS reports.
Effectiveness Reviews	• In conjunction with the responsible Division Director, selects the Effectiveness Review team members for High Risk level issues. • Performs a quality assurance review of all High Risk level issues Effectiveness Reviews reports prior to completion and distribution. • Discusses Effectiveness Review results and recommended correction actions (as applicable) with Division Directors.
Lessons Learned	• Works with LBNL personnel to document and disseminate lessons learned and best practices briefings using the Lessons Learned and Best Practices Database. • Disseminate key elements of a RCA Report as a lessons learned via the Lessons Learned and Best Practices Database.
Data Monitoring & Analysis	• Performs analysis of incidents that meet the external reporting threshold for ORPS and PAAA NTS to determine statistical trends or recurring issues.

PAAA COORDINATOR

IMP ELEMENTS	RESPONSIBILITIES
CATS Database	• Reviews issues and corrective actions to determine if they are PAAA NTS/Internal reportable.
Causal Analysis	• Determines if issues meet the criteria for PAAA NTS-Reportable / Internal Reportable incidents. • Notifies OCA, Responsible Division Management and other affected organizations of PAAA implications.
CAP Development	• Performs a quality assurance review of all CAPS for PAAA NTS reportable incidents prior to completion and distribution, including those documented in ORPS or PAAA NTS reports.
Corrective Action Completion Verification	• Verifies completion of corrective actions, as required.
Effectiveness Reviews	• Validates effectiveness of completed corrective action(s) for PAAA NTS-reportable incidents.

RADIATION CONTROL MANAGER (RCM)

IMP ELEMENTS	RESPONSIBILITIES
CATS Database	• Reviews issues and corrective actions specific to 10CFR830 and 10CFR835, as appropriate.
Causal Analysis	• In conjunction with the PAAA Coordinator, determines if issues meet the criteria for PAAA NTS-Reportable incidents specific to 10CFR830 and 10CFR835. • Notifies OCA, Responsible Division Management and other affected organizations of PAAA implications.
Corrective Action Completion Verification	• Verifies completion of corrective actions, if required. • Ensures that objective evidence of corrective action completion for any PAAA NTS 10CFR835 reportable issue is uploaded in the CATS Database.
Effectiveness Reviews	• Validates effectiveness of completed corrective action(s) for PAAA NTS-reportable incidents.

ORPS COORDINATOR

IMP ELEMENTS	RESPONSIBILITIES
CATS Database	• Reviews issues and corrective actions that are ORPS reportable.
Causal Analysis	• In conjunction with the Responsible Division Management, determines if issues meet the criteria for ORPS reportable incidents in accordance with LBNL/PUB-3000, Chapter 15, *Occurrence Reporting*. • Notifies OCA, Responsible Division Management and other affected organizations of ORPS implications.

ENVIRONMENTAL, HEALTH, AND SAFETY (EHS) DIVISION DIRECTOR

IMP ELEMENTS	RESPONSIBILITIES
Causal Analysis	• Determines if issues meet the criteria for a Type A or B incidents in accordance with LBNL/PUB-3000. • Notifies OCA, Responsible Division Management and other affected organizations of the incident implications. • Notify the DOE Berkeley Site Office (BSO). • Determine if LBNL will perform a concurrent investigation with the DOE.

OFFICE OF INSTITUTIONAL ASSURANCE (OIA) DIRECTOR

IMP ELEMENTS	RESPONSIBILITIES
Causal Analysis	• Determines if an issue is owned by multiple Divisions. • In conjunction with OCA, selects the RCA and Extent of Condition Review team(s) for issues that are not owned by a single Division in accordance with LBNL/PUB-5519(2). • Charter the RCA and Extent of Condition Review team(s) for issues that are not owned by a single Division prior to initiation of the RCA and Extent of Condition Review activities.

Attachment 1 – Definitions / Acronyms

Action to Preclude Recurrence – A corrective action designed to prevent the cause of the issue from manifesting, thereby preventing the issue from recurring

Best Practice – A technique or methodology that, through experience and research, has been proven to reliably lead to a desired result. It may also be a recommendation, suggested process improvement, or management or division initiative.

Casual Factor – The mistake(s) or failure(s) that led to an actual adverse incident or near-miss situation.

Cognizant Manager (CM) – The line manager responsible for ensuring that issues management is effectively implemented. This includes ensuring that issues and corrective actions are documented, managed and tracked through resolution; assigning personnel to perform or participate in causal analysis and extent of condition reviews and develop CAPs; and notifying external reporting coordinators of issues when they are identified.

Compensatory Action – A corrective action that is taken to address the condition, but not necessarily the cause of the issue**.**

Corrective Action – An action that eliminates a deficiency and/or the cause of an issue, and prevents or significantly reduces the likelihood of the same problem occurring again.

Corrective Action Plan (CAP) – A formal, documented plan developed and implemented by Division Management that addresses how an issue will be addressed and resolved through closure. Elements of a CAP include: immediate/compensatory measures taken to bring a process or program back into control, the cause and extent of condition of the issue, actions necessary to resolve and prevent recurrence of the issue, the name of the responsible person(s) for a particular corrective action and the expected completion date for each corrective action.

Effectiveness Review (ER) – A review of implemented corrective actions that is performed six to twelve months following an Issue closure to determine the effectiveness of any actions taken to preclude recurrence of the issue. The review should confirm that the completed corrective actions to preclude recurrence are sustainable, have prevented occurrence of similar issue(s) due to similar cause(s) and have not produced unintended consequences.

Enterer – A generic term used to identify the individual who enters the issue and corrective action information into the CATS database.

Extent of Condition (EOC) – The extent to which an identified issue has the potential to impact other activities, projects, programs, facilities, organizations or processes or has done so in the past. The extent of condition is used to determine if corrective action development and implementation is localized or applies across multiple activities, locations and/or systems.

Formal Assessment – An assessment, such as internal independent audit/surveillance, external or self assessments, etc. that are performed by an assigned Lead Assessor or Assessment Team. The formal

assessment requires the generation of a formal report, identification of findings, documentation of corrective action and follow-up activities.

Finding – A term that is interchangeable with "Issue". It is a generic term used to refer to programmatic or performance deficiencies, nonconformances, regulatory or procedural noncompliances, procedure inadequacies, assessment findings, external oversight findings, and associated actions that require formal corrective action. This includes, but is not limited to, a failure, defect, deviation, malfunction, deficiency, nonconformance of plant equipment, materials, procedures, personnel safety concerns or events which have or could have an effect on the safe, reliable, or efficient operation of the Laboratory, or which involve a failure to be in compliance with established external or internal requirements.

Initiator – A generic term used to identify the individual who identified or discovered the issue.

Issue – It is a generic term used to refer to programmatic or performance deficiencies, nonconformances, regulatory or procedural noncompliances, procedure inadequacies, assessment findings, external oversight findings, and associated actions that require formal corrective action. This includes, but is not limited to, a failure, defect, deviation, malfunction, deficiency, nonconformance of plant equipment, materials, procedures, personnel safety concerns or events which have or could have an effect on the safe, reliable, or efficient operation of the Laboratory, or which involve a failure to be in compliance with established external or internal requirements.

Immediate Action – A corrective action that immediately mitigates the issue.

Immediately-corrected Item – An issue that is corrected immediately or fixed on-the-spot.

Issue Category – A general category in which an issue may fall. Examples include: Accounting, Cryogenics, Electrical, Seismic, General HR, Lasers, Project Management, etc.

Observation – A practice or condition that is not technically noncompliant with an external or internal regulation or requirement, but could lead to noncompliance if left unaddressed.

Occurrence Reporting and Processing System (ORPS) – A system that notifies and keeps Laboratory management and applicable elements of the Department of Energy (DOE) informed of abnormal occurrences that could adversely affect:

a) the health and safety of employees, guests, visitors, and the general public;
b) the environment;
c) the intended purpose of LBNL facilities; or
d) the credibility of the DOE and/or LBNL.

Price Anderson Amendment Act (PAAA) Non-Tracking System (NTS) – A system that Laboratory management complies with to report adverse incidents to the DOE Office of Enforcement that could result in a reduction of fee or a discontinuation of a program or project.

Quality Assurance Review – A review of a Causal Analysis and Effectiveness Review Reports that is completed by the Office of Contractor Assurance to ensure that the report is credible, technically sound and accurate.

Recommendation – A practice or condition that is not a noncompliance, but is a suggested way of improving a practice or condition.

Responsible Person – A generic term used to identify the individual who will implement or is responsible for implementation of, or is the point of contact for a particular corrective action.

Reviewer – A generic term used to identify the individual who reviews and/or approves, issues, corrective actions, corrective action plans, objective evidence, etc.(e.g. SMEs, Division Safety Coordinators, designated independent parties).

Root Cause – The root or basic cause of an Adverse Condition that, if corrected, will preclude recurrence or greatly reduce the probability of recurrence of the same or similar adverse conditions(s). The root cause does not apply to the identified condition only, but has generic implications to a broad group of possible occurrences and is the most fundamental aspect of the cause that logically can be identified and corrected. The root cause is typically one level beyond the apparent cause.

Significant Adverse Condition – An issue that meets one or more of the following criteria:

- Significantly impacts the research activities or operation of LBNL
- Requires immediate notification to external regulatory agencies (e.g., DOE Office of Health, Safety and Security, U.S. Nuclear Regulatory Commission)
- Results in fines levied by external regulatory agencies (for financial penalties greater than $100K)
- Prevents UC from maintaining its contract with DOE to operate LBNL
- Results in considerable negative publicity or public opinion
- Results in losses greater than $1M
- Results in excess costs due to inefficiencies greater than $1M
- Presents a significant hazard to the safety and health of workers, environment or public Constitutes an adverse trend or inclination over an extended period of time, or is a recurring issue, as determined by formal performance evaluation or data monitoring and analysis.

Supersede – To replace one issue and/or corrective action with another. Superseding issues and/or corrective actions is done when individual issues will be addressed at an institutional level and when the institutional issue and associated corrective actions are documented and managed through resolution in the CATS Database.

Validation – The act of reviewing, checking or otherwise determining whether the corrective action(s) has been effective in mitigating the issue and preventing recurrence of the same or similar issue due to the same or similar causes. Validation is performed by someone (or persons) who did not perform the work associated with the corrective action(s).

Verification – The act of reviewing, checking or otherwise determining and documenting whether the corrective actions address the issue and have been implemented as required. Verification is performed by someone who did not perform the work associated with the corrective action(s).

Attachment 2 – Extension Requests

Extension requests are used for extenuating circumstances that impact completion of a corrective action by its original due date. Extension requests are not used for corrective actions that will not be completed on time due to lack of oversight, accountability, etc., with the exception of certain criteria outlined below.

Reviewers of extension requests are the same as those who reviewed the original issue and corrective action(s). A representative from OCA is included as a Reviewer for all High and Medium Risk level issues extension requests. Once an initial extension has been granted for a corrective action, any subsequent extensions will require the approval of the Chief Operating Officer (COO) or Deputy COO. Extension requests must be made at least two weeks (14 days) in advance of the current due date in order to be considered for approval.

Responsible persons and their CMs are reminded of the impending corrective action due date 60, 45, 30 and 15 days prior to the corrective action due date, as well as 15, 30 and 45 days past the due date.

When completing a justification for a corrective action extension request, the following criteria must be met:

1. The reason for the extension request is clearly and accurately stated.
2. A request due to resource issues must meet one of the following criteria:
   a. Completion of a corrective action is contingent upon another corrective action,
   b. Completion of a corrective action is dependent upon external contractors or resources, OR
   c. Completion of a corrective action is a subject matter with limited resources that has experienced a staffing reduction.
3. A request due to changing priorities must meet the following criteria:
   a. Line management reprioritizes due to unforeseen events or activities OR
   b. Project scope, process, or cost has changed.

Extension Request Activities

For High and Medium Risk level issues, perform the following:

Enterer

1. Discuss extension justification and obtain approval from the following organizations:
   - Significant Adverse Condition: Division Director
   - PAAA NTS Reportable: PAAA Coordinator
   - ORPS Category 1, R, or 2 Reportable: ORPS Coordinator
   - Type A or B Accidents: EHS Division Manager
   - Internal Formal Assessments: Division Director
   - External Formal Assessments: Lead Assessor

2. Complete the Extension Request and provide justification in the CATS database.

3. Identify and route to the appropriate Reviewer(s).

Reviewer

1. Review the Extension Request and justification in accordance with the criteria stated above.

2. Resolve any issues with the Enterer.

3. Approve or deny the extension request.

For Low Risk level issues, perform the following:

Enterer

1. Complete the Extension Request and provide justification in the CATS Database.

2. Notify affected organizations of the change, if applicable.

3. Identify and route to the appropriate Reviewer(s).

Reviewer

1. Review the Extension Request and justification.

2. Resolve any issues with the Enterer.

3. Approve or deny the extension request.

Attachment 3 – Extent of Condition Review Guidance

An Extent of Condition (EOC) Review is a process by which LBNL can identify the potential for an issue to exist and/or has occurred in other activities, processes, programs, organizations or elsewhere in the Laboratory. EOC Reviews are required for High Risk level issues. Upon identification of High Risk level issues, divisions should contact OCA for guidance on performance of Extent of Condition Reviews. EOC Reviews may be included as part of the Root Cause Analysis.

Extent of Condition Review Elements

Areas to be covered as part of an EOC Review may include the following:

- Looking for the same problem in areas other than where originally found
- Looking for other manifestations of the identified root or underlying causes of the problem
- Looking for similar / related problems or anticipating problems based on the identified issue
- Reviewing prior implementation / applications of the deficient process or procedure to see if earlier deficiencies have gone unnoticed

Extent of Condition Review Steps

During the EOC Review, the following steps should be performed, as appropriate:

- Review the circumstances and conditions that led to the identification of the issue
- Determine the activities or facilities to which the issue applies
- Review the underlying causes identified in the investigation and analysis
- Develop lines of inquiry or a checklist to determine scope of the review
- Use responses to the lines of inquiry or checklist to identify the extent of applicability to other activities, processes, equipment, programs, facilities, operations, and organizations, etc.
- Document the results of the review in the RCA Report or in a separate report, including recommended corrective actions

Attachment 4 - Extent of Condition Review Report Preparation Guidelines

The following report elements are provided as guidance when preparing an Extent of Condition Review Report separate from the RCA Report.

1. Cover page identifying the Team member name(s), signature(s) and date of completion.

2. Extent of Condition Review Title and/or Number.

3. Executive Summary (Identify the purpose and scope of the review.)

4. Background (Describe the circumstances and details surrounding the event/issue.)

5. Review of the Methodology (Sample size and basis for determining sample size.)

6. Lines of Inquiry (Identify the criteria used to evaluate the event/issue. Below are examples of Lines of Inquiry.)

    - What are the requirement(s)/policy for the area evaluated?
        a. External requirements
        b. Internal requirements

    - Are the requirement(s)/policy or practice(s) adequate and acceptable?

    - Do internal controls exist? Are internal controls adequate and implemented?
        a. Administrative Controls: Examples: policies, procedures, PM schedules, testing schedules, training, management availability/awareness, rotating work schedules
        b. Engineering Controls: Examples: self-capping syringe needles, ventilation systems such as a fume hood, sound-dampening materials to reduce noise levels, safety interlocks, radiation shielding, automatic-start generators

    - Does the same or similar problem exist in applications, locations or facilities other than where originally found? Have the same or similar problems occurred prior to this event?

    - Are there other manifestations of underlying causes of the problem?

    - Are there similar or related problems, or problems that can be anticipated based on the identified problem?

7. Results of the Extent of Condition Review (Describe the pervasiveness or extent of the event/issue. Provide a statement of results of the evaluation and any actions currently being performed to mitigate the issues or risks.)

8. Recommended Corrective Actions (Identify recommendations that will mitigate or prevent the event/issue from recurring.)

Attachment 5 – Corrective Action Plan Development and Template

Corrective Action Plan (CAP) Development

A CAP can be documented in a separate document or in the ORPS and/or PAAA NTS Report. The CAP must be approved by the Responsible Division Director(s) authorized to provide the resources (funding, personnel and time) required to successfully implement the corrective action(s). This may involve coordination among various Divisions to complete a single, comprehensive CAP. A Template for the CAP follows.

The Assessment Report and/or Root Cause Analysis Report includes a clear description of the findings and/or causes and corrective actions that provide the base for developing the CAP.

CAP Development Activities

1. The Responsible Division should assess each finding/cause as documented in the Report and the associated recommended corrective action to determine the most appropriate corrective actions to implement. The appropriate corrective action(s) must address the findings/root causes and prevent recurrence of similar issues. Corrective actions to preclude recurrence should have the following attributes:
    a. Address the root or apparent cause(s) and contributing cause(s), if corrective actions to preclude recurrence were created for the contributing cause(s),
    b. Are implemented as intended,
    c. Prevent occurrence of similar condition(s) due to similar cause(s),
    d. Demonstrate endurance and sustainability,
    e. Have not introduced negative unintended consequences, and
    f. Improve process/program performance.

2. The Responsible Division should include the corrective actions that will be implemented to address the finding(s)/root cause(s) and prevent recurrence in the CAP. Immediate and compensatory corrective actions also should be included in the CAP. Corrective Actions should be Specific, Measurable, Accountable, Reasonable and Timely *(Refer to BLI2010: Corrective Action Development Training).*

Specific	Describe the action(s) that will address / fix the root or apparent cause and prevent recurrence.
Measurable	Completion of the corrective action(s) should be verifiable through objective evidence.
Accountable	Responsibility for implementing the action(s) should be defined and documented.
Reasonable	Corrective action(s) should be feasible (a standard control measure.)
Timely	Corrective action(s) should be implemented in a realistic timeframe to prevent recurrence. The expected completion date for each corrective action should be documented.

3. The Responsible Division should ensure that two standard corrective actions for High Risk level issues are included in the CAP. The standard corrective actions are:
    1. Perform an Effectiveness Review, and
    2. Submit a Lessons Learned Briefing **(*for ORPS category 1 and R reportable events*)**

4. Prior to the quality assurance review, the Responsible Division should submit the CAP to the following individuals / entity for review, as follows:
    a) Significant Adverse Condition issues: OCA
    b) PAAA NTS-Reportable Incidents: PAAA Coordinator
    c) ORPS Category 1, R, or 2 Reportable events: ORPS Coordinator
    d) Type A or B Accidents: Environment Health & Safety Division Director
    e) External Formal Assessments (for High and Medium Risk level issues): OCA
    f) Other applicable parties as determined by the Responsible Division

5. The Responsible Division must submit the CAP to OCA for a quality assurance review prior to finalizing and distribution to appropriate parties for all High Risk level issues, including those documented in ORPS and/or NTS Reports.

6. The Responsible Division approves the CAP and determines if the CAP will be submitted to the BSO for concurrence / approval.

7. Once the CAP is approved by the Responsible Division Director(s), Responsible Division Management ensures that the issue and associated corrective actions are entered into the CATS Database and managed through resolution in accordance with this manual and the OIA-OCA-0001, Rev.3 *Corrective Action Tracking System (CATS) Database User Manual.*

Corrective Action Plan Template

(In the Header of each page in the CAP)
Name of Assessment / Incident, Month, Day, Year
Corrective Action Plan, Month, Day, Year

LAWRENCE BERKELEY NATIONAL LABORATORY
XYZ ASSESSMENT / XYZ INCIDENT
CORRECTIVE ACTION PLAN

Month Day, Year (issued)

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1.0 EXECUTIVE SUMMARY

2.0 FINDINGS

2.1 FIND-001:

State the issue/finding verbiage identified in formal assessment report.

REQUIREMENT NOT MET:

State the requirement citation (Order, Part, Section, Step, etc.) identified in the formal assessment report. If none is cited, then indicate no requirements were cited in the assessment report.

CAUSAL ANALYSIS:

Using the Assessment Report, other associated documentation and/or interviews with appropriate personnel, make a determination of what the apparent cause of the issue is.

If a formal Root Cause Analysis is required, reference the RCA in this section.

IMMEDIATE/ COMPENSATORY ACTIONS:

Corrective Action 1-1

State the immediate action that immediately mitigated the issue or the compensatory action that was taken to address the condition, but not necessarily the cause of the issue. If multiple immediate/ compensatory actions were taken, separately identify them by adding additional sections (e.g. CA 1-1, CA 1-2, etc.). These actions must be clearly described and should not be ambiguous or general in nature.

An example of an immediate action: Lockout/Tagout a piece of equipment to immediately mitigate the issue.

An example of a compensatory action: Retrain people on proper Lockout/Tagout procedures.

Projected Completion Date: (Specify for each corrective action): Identify the expected completion date for this action. If the action has already been completed, identify the date the action was completed.

Responsible Person: Identify the name of the person responsible for the immediate/ compensatory action.

ACTIONS TO PRECLUDE RECURRENCE:

Corrective Action 1-2

State a single corrective action that is designed to prevent the cause of the issue from manifesting thereby preventing the issue from recurring. If multiple actions will be performed for this issue, separately identify them by adding additional sections (e.g. CA 1-3, CA 1-4, etc.). These actions must be clearly described and should not be ambiguous or general in nature.

An example of an action to preclude recurrence: Revise the pre-operational checklist to include a Lockout/Tagout check to ensure safe conditions prior to daily operations.

Projected Completion Date or Completion Date (Specify for each corrective action): Identify the expected completion date for this action. If the action has already been completed, identify the date the action was completed.

Responsible Person: Identify the name of the person is responsible for the corrective action.

Note: if a corrective action will require significant time to implement, document interim actions or compensatory measures to prevent recurrence while the correction is pending completion.

3.0 OBSERVATIONS (if applicable)

Observations are documented in this section of the CAP if lab management determines or makes an established agreement with the assessment entity that an observation will be formally addressed.

3.1 OBS-001:

State the observation verbiage identified in formal assessment report.

RESPONSE:

Response 1-1

State the response that addresses the issue. If multiple responses are necessary for this observation, separately identify them by adding additional sections (e.g. Response 1-1, Response 1-2, Response 1-3, etc.). If the response indicates that an action(s) will be taken, identify the Projected Completion Date and the Responsible Person for the action(s).

Projected Completion Date or Completion Date (Specify for each action): Identify the expected completion date for this action. If the action has already been completed, identify the date the action was completed.

Responsible Person: Identify the name of the person that is responsible for the action.

4.0 ATTACHMENTS (IF APPLICABLE)

Attachment 1 - Objective Evidence of Corrective Actions Completed Prior to Issuance of the CAP

Attachment 2 – Formal Root Cause Analysis/ Extent of Condition Report

Attachment 6 – Effectiveness Review Guidance

Effectiveness Reviews are required for all High Risk level issues (Significant Adverse Conditions, PAAA-NTS reportable incidents, ORPS category 1, 2 or R reportable incidents, and Type A or B accidents) because of their seriousness and importance. Effectiveness Reviews for less significant issues may be initiated at the discretion of a CM in order to identify opportunities for improvement and to ensure corrective actions were effectively implemented. Effectiveness Reviews are typically completed 6-12 months after the issue is closed. Immediate and Compensatory corrective actions are not included in the Effectiveness Review.

The Responsible Person who has ownership of performing the Effectiveness Review is responsible for contacting the OCA prior to performance of the review. OCA will provide technical guidance to the Effectiveness Review team during performance of the review. Performance of the review includes planning and scheduling review activities, developing lines of inquiry, and gathering, analyzing and maintaining objective evidence. After performance of the Effectiveness Review, the CM should consider the establishment of periodic reviews of effectiveness through self-assessments, audits and/or surveillances.

An Effectiveness Review is a validation that a corrective action was implemented as designed, addresses the root cause(s) of the incident and prevents recurrence of similar, future events. Effective corrective actions to preclude recurrence share the following generic attributes:

1. Address the Root Cause and, if corrective actions to preclude recurrence were created for them, the primary Contributing Cause(s).

2. Are implemented as intended.

3. Prevent occurrence of similar condition(s) due to similar cause(s).

4. Demonstrate endurance and sustainability.

5. Have not introduced negative unintended consequences.

6. Improve process/program performance.

Below are the Effectiveness Review Ratings Definitions:

- **Effective** - Corrective actions are implemented as intended, have addressed the causes of the issue / finding, will prevent recurrence of the issue/ finding and demonstrates sustainability. No new corrective actions are recommended.

- **Partially Effective -** Corrective actions are implemented as intended, and have partially addressed the causes of the issue / finding, but does not prevent recurrence or demonstrate sustainability. Revised or new corrective actions are recommended to enhance the effectiveness of the correction action.

- **Ineffective** - Corrective actions were not implemented as intended, does not address the causes of the issue / finding, does not effectively prevent recurrence of the issue / finding, and does not demonstrate sustainability. New corrective actions are recommended to enhance the effectiveness of the corrective actions.

Approach to performing an Effectiveness Review

Effectiveness Reviews for all high risk issues may be scoped and performed using one or more of the methodologies described below, as appropriate. The responsible division management, with assistance from the Office of Contractor Assurance, can determine the appropriate methodology (or methodologies) to use based on the issue, cause(s) and corrective action(s) pertaining to the Effectiveness Review. More than one methodology may be used to perform the Effectiveness Review.

Methodology #1
An Effectiveness Review of individual corrective actions implemented to address a single incident or assessment where corrective actions are completed within a one year period.

Methodology #2
An Effectiveness Review of sequential corrective actions implemented to address a single incident or assessment where the corrective actions will be collectively evaluated to determine the effectiveness of implemented corrective actions. All corrective actions will be validated as implemented and the entire suite of corrective actions, not the individual corrective actions, will be assessed for effectiveness.

Methodology #3
An Effectiveness Review of corrective actions implemented to address a single area of exposure, such as electrical safety, will be scoped and performed as one review. This review involves evaluating corrective actions from two or more related incidents, with similar conditions and causes, and collectively assessing their implementation and effectiveness in addressing the cause(s) of the exposure area and preventing recurrence. Related corrective actions will be validated as implemented and the entire suite of corrective actions, not the individual corrective actions, will be assessed for effectiveness.

An Effectiveness Review also can be performed through a formal self-assessment or an independent assessment that includes an evaluation of the corrective actions to determine effectiveness. This evaluation should include planning (developing lines of inquiry), interviewing appropriate parties and using tools to document the evaluation.

Acceptable methods to evaluate effectiveness of an implemented corrective action include:

- Observation of work performance
- Use of performance measure and indicators to track and trend the number and frequency of recurrences
- Performance testing
- Personnel interviews to determine understanding and compliance with the implemented actions

- Review of source documentation of implemented corrective actions

Resources to use to perform an Effectiveness Review

- The Assessment Report and/or Root Cause Analysis / Extent of Condition Report that pertains to the issue.
- A list of implemented corrective actions that address the issue.
- Objective evidence of corrective action(s) completion and closure.
- Effectiveness Review Methodology, Analysis and Report Templates.

Effectiveness Review Activities

I. Responsible Person

1. After closure of an issue, work with OCA to schedule an Effectiveness Review of corrective actions to prevent recurrence.

II. Division Director

1. In conjunction with OCA, select a team and ensure that an Effectiveness Review is performed in accordance with this manual.
2. Generate a formal charter for the Effectiveness Review team that states the commission and expectation of the team.
3. If the Effectiveness Review determines that the corrective action(s) to prevent recurrence were ineffective, perform the following:
    i. Determine the corrective actions that will be implemented to prevent recurrence.
    ii. Initiate an entry in CATS to document that corrective action(s) were not effective and the corrective actions that will be implemented.

III. OCA

1. Provide oversight and training to the Effectiveness Review Team.
2. If the Effectiveness Review determined that the actions to preclude recurrence were ineffective, discuss the results with responsible Division Director and other personnel as appropriate.
3. Maintain the completed Effectiveness Review data package.

IV. Effectiveness Review Team

1. Perform an Effectiveness Review in accordance with Attachment 6 in this manual, which includes planning and scheduling review activities, developing lines of inquiry, gathering, analyzing and maintaining objective evidence.

2. Document the results of the Effectiveness Review, including recommendation of additional corrective actions as necessary, in a report in accordance with Attachment 7 – *Effectiveness Review Templates, Effectiveness Review Report.*

3. Maintain supporting objective evidence of the Effectiveness Review.

4. Submit the draft Effectiveness Review report to OCA for a quality assurance review prior to distribution of the report.

5. Submit the draft Effectiveness Review report to responsible line management for a factual accuracy review prior to distribution of the report.

6. Resolve concerns with OCA and responsible line management, as necessary.

7. Sign the final Effectiveness Review report and submit the report to the Responsible Division Director.

8. Compile and submit a data package including all of the supporting documentation to OCA.

Attachment 7 – Effectiveness Review Templates

Effectiveness Review Methodology Template

Effectiveness Review Methodology Template is used to develop and document the Lines of Inquiry LOI). The LOI includes:

a) **Document Review:** objective evidence that the corrective actions was implemented, will prevent recurrence and demonstrates sustainability.
b) **Interviews**: testimony from individuals who are responsible for: 1) implementing the corrective action, 2) adhering to the corrective action, and 3) overseeing compliance.
c) **Observation of work performed** (as applicable).

Effectiveness Review Methodology – *(Insert Effectiveness Review Name)*

Root Cause: **Corrective Action #**	
METHODOLOGY	**EVALUATION**
DOCUMENT REVIEW	
Document #1	
Insert the title of the document followed by the lines of inquiry	*Document the Team's evaluation of the document as it relates to addressing the root cause of the incident and preventing recurrence.*
Document #2	
Document #3	
OBSERVATION OF WORK	
Work Process *Insert title of the work process to be observed followed by lines of inquiry.*	*Document the Team' observation of how the process if performed.*
PERSONNEL INTERVIEWS	
Name of Interviewee #1	
Insert the name of the individual interviewed followed by the lines of inquiry.	*Summarize the interviewees' response to the questions.*
Name of Interviewee #2	
Name of Interviewee #3	
Name of Interviewee #4	

Effectiveness Review Analysis Template

The Effectiveness Review Analysis Template is used to evaluate the effectiveness of each corrective action based on the criteria.

Effectiveness Review Analysis – (Insert Effectiveness Review Name)

Root Cause: **Corrective Action:**							
CORRECTIVE ACTION EFFECTIVENESS							
CRITERIA		**YES**		**PARTIALLY**		**NO**	**JUSTIFICATION**
1. Does the corrective action address the root cause?							
2. Does the corrective action prevent recurrence of similar conditions due to similar causes?							
3. Has the corrective action been implemented as intended?							
4. Does the corrective action demonstrate endurance and sustainability?							
5. Has the corrective action introduced negative unintended consequences?							
6. Has the corrective action improved the program/process performance?							

Effectiveness Review Report Template

Effectiveness Review Report for the {Name Of Effectiveness Review Title} Corrective Actions

Report Prepared By:

Type Name of Team Member, Division/Department	Date
Type Name of Team Member, Division/Department	Date

Approved By:

Division Director	Date

Effectiveness Review Report for the {Name Of Effectiveness Review Title} Corrective Actions

Description of Incident/Finding:

Effectiveness Review Conclusion:

Corrective Action #	*Corrective Action Description*	*Effective*			*Justification*
		Yes	*Partially*	*No*	

Recommended Corrective Actions:

Rating Definitions:

- **Effective *(Yes)***—Corrective actions are implemented as intended, have addressed the causes of the issue / finding, will prevent recurrence of the issue/ finding and demonstrates sustainability. No new corrective actions are recommended.
- **Partially Effective *(Partially)*** —Corrective actions are implemented as intended, and have partially addressed the causes of the issue / finding, but does not prevent recurrence or demonstrate sustainability. Revised or new corrective actions are recommended to enhance the effectiveness of the correction action.
- **Ineffective *(No)***—Corrective actions were not implemented as intended, does not address the causes of the issue / finding, does not effectively prevent recurrence of the issue / finding, and does not demonstrate sustainability. New corrective actions are recommended to enhance the effectiveness of the corrective actions.

Attachment 8 – Risk Level and Significance Code Guidance

Table 1 – RISK LEVELS

Risk Level	Type/Description of Issue
High	• Significant Adverse Condition (SAC) • PAAA NTS-Reportable Incident • ORPS Category 1, R, or 2 Incident • Type A or B Accident • Other Issues as designated by management
Medium	• Adverse Condition identified through Formal Assessment • PAAA Internally-Reportable Incident, as determined by management • ORPS Category 3 Reportable Incident • Other Issues as designated by management
Low	• Worker Safety & Health Issues that do not fall into High or Medium Risk Levels • Adverse conditions not identified through Formal Assessment • Other issues that do not meet the thresholds identified in the High or Medium risk levels.
De Minimis	• Selected only when the level of risk is too small to be concerned with. • Worker Safety and Health Issues when there is no direct or immediate relationship to the environment, safety, or health and are not included in citations

Table 2 – SIGNIFICANCE CODES

Significance Code	Type/Description of Issue
Significant Adverse Condition (SAC)	Programmatic or performance deficiencies that could significantly impact the safety, operations, research activities of the LBNL or present a significant hazard to the safety and health of the worker, environment or public. These may be identified through actual events and internal or external assessment.
PAAA Reportable Incident	Meets the PAAA-reportable incident threshold as determined by the PAAA Coordinator in accordance with the PAAA Program Manual.
ORPS Reportable Incident	Meets the ORPS-Reportable incident threshold as determined by the ORPS Coordinator in accordance with LBNL/PUB-3000, Chapter 15, *Occurrence Reporting.*
Type A or B Accident	Meets the threshold for a Type A or B incident as determined by the EH&S Division Manager.

Attachment 9 – Issues Management at a Glance

1. Cognizant Manager, ensures that OCA, EHS Management, the PAAA Coordinators, the ORPS Coordinator, and other management, as appropriate, are notified of an incident or finding from a formal internal or external assessment.

2. OCA, EHS Management, PAAA Coordinator(s), ORPS Coordinator, and other management, as applicable, determine whether the event or finding is a Significant Adverse Condition, PAAA NTS reportable incident, ORPS Category 1, 2, or Recurring incident, or Type A or B incident.

3. Division Director, if the event or issue falls into one of the aforementioned categories, perform the following:

    - Assemble a Root Cause Analysis (RCA) team to perform an RCA in accordance with LBNL/PUB-(2), *Causal Analysis Program Manual.*

    - Assemble the same team or a new team to perform an Extent of Condition Review in accordance with LBNL/PUB-5519(1), Attachments 3 – *Extent of Condition Review Guidance* and 4 – *Extent of Condition Review Report Preparation Guidelines.*

    - Upon completion of the RCA and EOC, develop a Corrective Action Plan in accordance with LBNL/PUB-5519 (1), Attachment 5 – *Corrective Action Plan Development and Template.*

    - Ensure OCA and other internal organizations review the CAP and that comments are resolved prior to issuance.

    - Submit the data package (i.e. CAP, RCA report, EOC Report) to appropriate management/ organizations and OCA, and retain a copy of the data package in the Division Records.

    - Ensure that an Effectiveness Review is performed 6-12 months after completion of the final corrective action in accordance with LBNL/PUB-5519 (1), Attachments 6 – *Effectiveness Review Guidance* and 7 – *Effectiveness Review Templates*.

    - Upon completion of the Effectiveness Review, submit a copy to OCA and retain a copy in the Division Records.

    - Ensures that additional corrective actions that are identified as a result of the Effectiveness Review are entered into the CATS Database.

4. Cognizant Manager ensures that all issues and corrective actions are entered into the CATS Database and are resolved by the due dates.